

## **SCHEDULE 4**

SUMMARY OF RESULTS  
SECTION 1.0: DAY 7 RAW (NON-NORMALIZED) PLASMA DILTIAZEM  
Mean Pharmacokinetic Parameters for Raw Plasma Diltiazem  
(n=23)

Parameter	Biovail ER (A) 1 x 120 mg	Biovail ER(B) 1 x 240 mg	Biovail ER (C) 1 x 300 mg
	Arithmetic Mean (%CV)	Arithmetic Mean (%CV)	Arithmetic Mean (%CV)
AUC (0 - $\tau^*$ )(ng·hr/mL)	886.61 (25.64)	2217.41 (27.80)	2799.66 (22.86)
C <sub>max</sub> (ng/mL)	61.34 (29.40)	149.89 (34.26)	193.06 (27.45)
C <sub>min</sub> (ng/mL)	19.50 (39.32)	51.56 (43.55)	60.65 (44.37)
T <sub>max</sub> (hours)	9.96 (28.96)	10.13 (22.53)	9.61 (25.63)
Degree of Fluctuation (%)	114.74 (36.96)	108.23 (35.34)	114.55 (37.60)

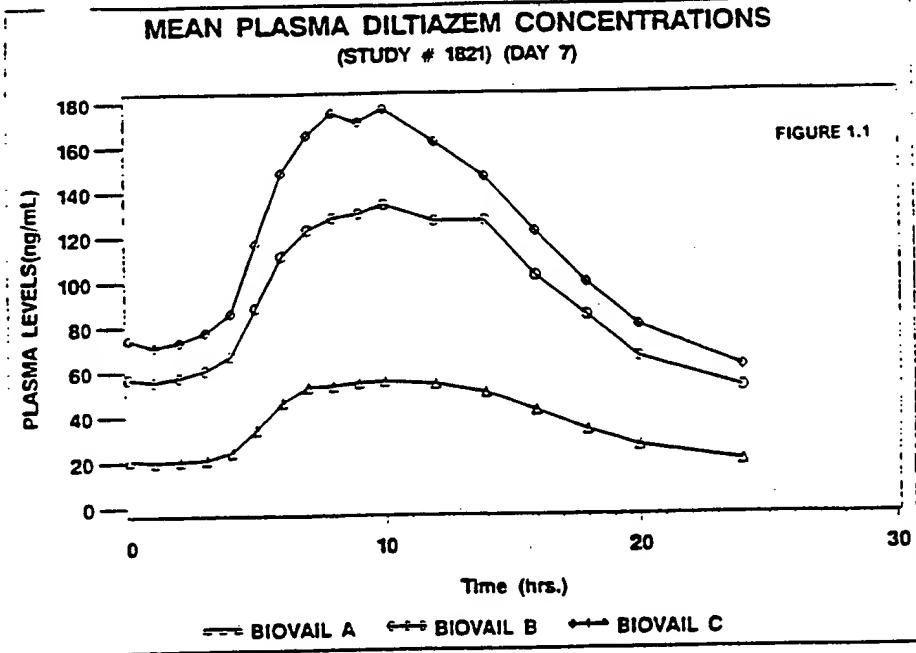
\* $\tau$  = 24 hours

Linear Regression Analyses

	Intercept	Slope	r <sup>2</sup>
AUC (0 - $\tau^*$ )	-384.80	10.69	0.95
C <sub>max</sub>	-26.43	0.73	0.91
C <sub>min</sub>	-7.60	0.23	0.87

\* $\tau$  = 24 hours

RAW DATA



**SUMMARY OF RESULTS**  
**SECTION 2.0: DAY 7 RAW (NON-NORMALIZED)**  
**PLASMA DESACETYLDILTIAZEM**

Mean Pharmacokinetic Parameters for Raw Plasma Desacetyldiltiazem  
(n=23)

Parameter	Bioavail ER (A) 1 x 120 mg Arithmetic Mean (%CV)	Bioavail ER(B) 1 x 240 mg Arithmetic Mean (%CV)	Bioavail ER (C) 1 x 300 mg Arithmetic Mean (%CV)
AUC (0 - $\tau^*$ )(ng·hr/mL)	143.37 (170.34)	369.90 (189.82)	462.39 (170.15)
C <sub>max</sub> (ng/mL)	8.08 (175.64)	18.40 (169.63)	23.47 (151.50)
C <sub>min</sub> (ng/mL)	5.07 (166.73)	13.38 (213.00)	15.85 (183.30)
T <sub>max</sub> (hours)	12.04 (28.04)	11.48 (35.42)	12.13 (28.26)
Degree of Fluctuation (%)	47.49 (53.53)	47.78 (60.75)	49.06 (48.58)

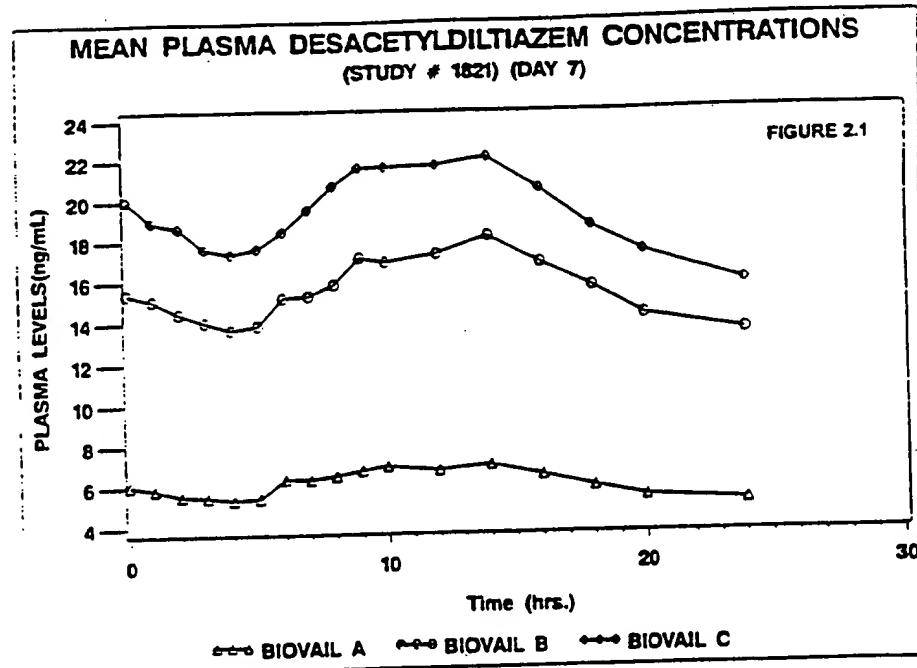
\* $\tau$  = 24 hours

**Linear Regression Analyses**

	Intercept	Slope	r <sup>2</sup>
AUC (0 - $\tau^*$ )	-68.31	1.79	0.96
C <sub>max</sub>	-2.18	0.09	0.94
C <sub>min</sub>	-2.03	0.06	0.89

\* $\tau$  = 24 hours

**RAW DATA**



**SUMMARY OF RESULTS**  
**SECTION 3.0: DAY 7 RAW (NON-NORMALIZED)**  
**PLASMA DESMETHYLDILTIAZEM**  
**Mean Pharmacokinetic Parameters for Raw Plasma Desmethyldiltiazem**  
(n=23)

Parameter	Biovail ER (A) 1 x 120 mg	Biovail ER(B) 1 x 240 mg	Biovail ER (C) 1 x 300 mg
	Arithmetic Mean (%CV)	Arithmetic Mean (%CV)	Arithmetic Mean (%CV)
AUC (0 - $\tau^*$ ) (ng·hr/mL)	372.35 (21.94)	798.90 (22.56)	1003.02 (18.83)
C <sub>max</sub> (ng/mL)	21.21 (24.51)	44.22 (25.55)	55.10 (19.48)
C <sub>min</sub> (ng/mL)	5.07 (166.73)	13.38 (213.00)	15.85 (183.30)
T <sub>max</sub> (hours)	11.83 (24.01)	12.52 (22.83)	12.48 (17.40)
Degree of Fluctuation (%)	63.09 (40.22)	58.21 (37.42)	60.37 (33.95)

\* $\tau$  = 24 hours

**Linear Regression Analyses**

	Intercept	Slope	r <sup>2</sup>
AUC (0 - $\tau^*$ )	-47.65	3.51	0.98
C <sub>max</sub>	-1.35	0.19	0.95
C <sub>min</sub>	-0.77	0.10	0.94

\* $\tau$  = 24 hours

**RAW DATA**

**MEAN PLASMA DESMETHYLDILTIAZEM CONCENTRATIONS**  
(STUDY # 1821) (DAY 7)

